



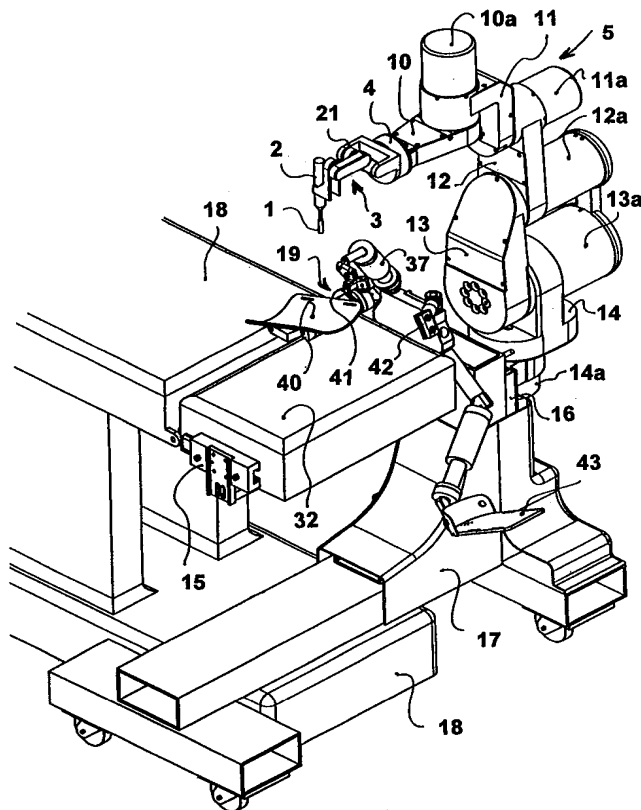
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(54) Title: ORTHOPAEDIC SURGERY APPARATUS FOR GUIDING A TOOL AND FOR SUPPORTING A LIMB

(57) Abstract

An apparatus for guiding a surgical tool (1), mounted on a mechanism (3) connected to a head (4) of a robotised positioning unit (5). The mechanism (3) defines a plane of movement integral to the head (4) which has a plurality of degrees of freedom, by means of arms (10, 11, 12, 13, 14) rotating with respect to one another. The positioning unit (5) is connected to a basement (17) movable on wheels under a surgical bed (18) and which can be secured to the latter. The positioning unit (5) brings the head (4) in a predetermined location of the space so that the tool (1) is located near the operation region, the plane of the mechanism (3) integral to the head (4) is parallel to the plane of a reference surface which has to be created on the bone, and the manually operated tool (1) cuts with the precision said reference surface parallel to such plane. An equipment (19) for the support of the leg and for reference to the knee is also provided. The apparatus allows the creation with precision of reference surfaces for implanting a prosthesis thereon.



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TITLE

ORTHOPAEDIC SURGERY APPARATUS FOR GUIDING A TOOL AND FOR
SUPPORTING A LIMB.

DESCRIPTION5 Field of the invention

The present invention relates to the field of orthopaedic surgery and, more precisely, it refers to an apparatus for guiding a tool handled by a surgeon during bone cutting operations when creating fixing and reference
10 surfaces for a prosthesis.

Furthermore, it refers to a supporting and reference equipment for limbs during cutting operations with said apparatus, as in particular, even if not exclusively, for the support of the leg and for reference to the knee
15 throughout surgical operations for setting a prosthesis.

Description of the prior art

The surgical practice for setting a prosthesis during orthopaedic surgery operations provides for the step of removing portions of the bone that has to be
20 corrected and the step of creating fixing and reference surfaces for the prosthesis.

For example, in the case of knee operations, the implant of a prosthesis is necessary for re-establishing a normal joint between femur and tibia. One of the steps of
25 the operation provides for the modification of the distal femur, which is removed and replaced by a prosthesis suitably shaped that re-builds the ideal surface of the joint thus accomplishing a correct sliding on tibia.

During the operation, more precisely, the knee of
30 the patient is appropriately kept still and the involved portions of the femur and of the tibia are exposed. Then, the surgeon with the cutting tool, normally consisting of pneumatic saws, removes the bone portions of the femur

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that have to be corrected by the prosthesis, making then manually the suitable reference surfaces and finishing them off.

5 It is therefore necessary a remarkable skill of the surgeon who, during the operation, finds out the correct reference axes of the prosthesis, previously calculated at the moment of its manufacture according to the most favourable calculated posture of the limb that has to be corrected.

10 Notwithstanding the high skill required to the surgeon, however, the identification of such axes without the help of a precise guide is subject to a high probability of error which cannot be easily reduced.

15 On the other hand, the prosthesis is calculated and manufactured with sophisticated means in order to correct, once implanted, the limb in the most favourable way. However, the precision with which the prosthesis has been made is useless if an error in the orientation thereof occurs.

20 A similar problem arises in the case of other surgical orthopaedic operations in which a prosthesis is implanted.

25 On the other hand, robotised guiding means are known which support the surgeon during the operation and guide the tool along predetermined trajectories preventing it from being moved wrongly. Such robotised means give to the surgeon an appropriate support when approaching the operation point but limit his finishing action, which is more delicate. Furthermore, they are often cumbersome and
30 are not suitable for being associated in a flexible and versatile way to a surgical bed.

Moreover, always throughout knee operations, for a correct fastening of the leg, the femur is currently supported at the thigh. The femur and tibia, however, are

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not fastened to any fixed support, but are firmly clasped by the assistants hands who prevent the leg from moving, as far as possible, during the bone cutting steps for the creation of the reference surfaces for the prosthesis.

5 Is then necessary, after having oriented properly the tool, to orient and fix properly also the leg by suitable means, currently not available.

Summary of the invention

10 It is, therefore, an object of the present invention to provide an apparatus for guiding a surgical tool during bone cutting operations that allows with precision the creation of reference surfaces for fixing a prosthesis.

15 It is, moreover, object of the present invention to provide such a guiding apparatus suitable for giving a valid help to the surgeon, providing appropriate support and not limiting his action for predetermined degrees of freedom.

20 It is a further object of the invention to provide such a guiding apparatus that is versatile when used in the operating room and in particular can be easily associated to a surgical bed.

 It is, then, object of the present invention to provide an equipment for precisely supporting a limb throughout orthopaedic surgical operations.

25 A particular object of the present invention is to provide an equipment for supporting the leg and the knee during such operations.

 These and other objects are achieved by the apparatus according to the present invention, whose
30 characteristic is to comprise:

- a robotised positioning unit having a plurality degrees of freedom, suitable for being braked in a chosen position,
- a support head mounted at the end of said positioning

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unit,

- a mechanism carrying the tool and connected to the head, the mechanism being suitable for moving manually the tool according to predetermined degrees of freedom with respect to the head.

In particular, in a preferred embodiment, the mechanism allows the tool to be operated manually in a plane, i.e. guided in such plane by the hand of the surgeon after that the positioning unit has, previously, oriented the plane in a predetermined way.

Advantageously, for the execution of different parallel cuts, means are provided for translating said mechanism orthogonally to said plane.

Preferably, the positioning unit comprises a basement suitable for being arranged under a surgical bed and kept integral to the latter. An equipment for the support and reference of a limb is provided, in particular for supporting the leg and for reference to the knee, comprising at least an orientable supporting arm mounted on the basement. At the arm end opposite to the base a couple of jaws is connected, in a way that can be adjustably oriented, clamping the limb and firmly supporting it near the operation region.

In a preferred embodiment of the equipment, at least a couple of jaws is provided for clamping the femur and located at the end of said arm. Furthermore, an adjustable supporting arm for the foot, an adjustable supporting arm for the thigh and an adjustable supporting arm for the tibia are provided fixed to the basement.

The support for the tibia may comprises screw means for direct penetration into the bone and a clamp for their orientation and tightening.

Alternatively, the support for the tibia may comprise jaws means, in the same manner of the femur.

Brief description of the drawings

Further characteristics and the advantages of the guiding apparatus and the equipment according to the present invention will be made clearer with the following description of an embodiment thereof, exemplifying but not

5 - figure 1 shows a perspective view of a guiding apparatus according to the present invention;

10 - figure 2 shows an elevational side view of the apparatus of figure 1 arranged in combination with a surgical bed and with an equipment for the support of the leg and the knee;

15 - figure 3 shows a partial and enlarged perspective view of a mechanism mounted at the top end of a positioning unit with representation of different positions of the tool in a same plane;

 - figure 4 shows the same perspective partial and enlarged view of figure 3 with the mechanism working in a different plane.

20 - figure 5 shows a elevational front view of the surgical bed on which an equipment is mounted for supporting the leg and for reference to the knee;

 - figure 6 shows a perspective partial more detailed view of jaws of the equipment of figure 5.

25 Description of the preferred embodiments

 With reference to figure 1, in a guiding apparatus according to the invention a tool 1, for example a rotating tool such as a mill operated by a motor 2 or operated by means of a transmission cable, is mounted on a

30 mechanism 3 connected to a head 4 of a positioning unit 5.

 As shown in figure 3, the mechanism 3 comprises at least a couple of rods 6, 7 having parallel axes that define a plane of movement integral to head 4. Positioning unit 5 has arms 10, 11, 12, 13 and 14, capable of rotating

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with respect to one another and operated by respective actuators 10a, 11a, 12a, 13a and 14a. Positioning unit 5 has therefore five rotational degrees of freedom, and a translational degree of freedom by means of a vertical slide 16 operated by an actuator not shown.

Positioning unit 5 is, moreover, connected to a basement 17, for example movable on wheels and which can be set under a surgical bed 18, shown in figure 2. Means are provided 15 at both sides of basement 17 for fixing positioning unit 5 to the surgical bed 18.

In an advantageous embodiment of the invention, as hereinafter described in more detail, surgical bed 18 is provided with an equipment 19 for the support and reference for a limb.

Before starting the cut of the surface on the bone to which the prosthesis has to be fixed positioning unit 5 moves head 4. More precisely, positioning unit 5 has a plurality of axes 10a, 11a, 12a, 13a, 14a associated to sensors of rotation that bring head 4 in a predetermined location of the space so that:

- tool 1 is located near the operation region;
- the plane integral to head 4 and containing rods 6 and 7 of mechanism 3 is parallel to the plane in which the bone reference surface has to be made;
- tool 1 moves parallel to such plane and cuts with precision such reference surface.

In order to cut a single reference surface for fixing the prosthesis more cutting steps may be necessary. Therefore, as shown in figures 3 and 4, a fork 21 is provided on head 4 between whose ends second rod 7 can translate by means of a micrometrical screw 20. This way, tool 1 can be translated in a plane parallel to the plane in which the previous cut has been executed without moving positioning unit 5, with the assurance that the cut is

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made with the chosen orientation and with an appropriate cutting depth.

At the end of the cutting steps of a first reference surface, a second reference surface can be cut which is
5 oriented differently, according to new co-ordinates calculated by means of a computer and a monitor not shown. The positioning unit, then, by means of actuators 10a, 11a, 12a, 13a, 14a above described, will move head 4 so that mechanism 3 lays in this new plane.

10 For such a machine that has to carry out so delicate operations, the combination of manual and robotised movements is the most favourable for the following reasons:

- manual sensitivity of the surgeon cannot be replaced by
15 any machine;
- the surgeon, in any case, is sure that the tool 1 moves only in the plane of the reference surface for the prosthesis;
- this plane can be quickly changed when another reference
20 surface has to be cut.

As shown in figures 2 and 5, surgical bed 18 is suited for orthopaedic operations since it has an end 32 which can be bent and to which the equipment 19 according to the invention for the support and reference of a limb
25 can be fixed by releasable lock means 33.

Equipment 19 comprises a base 35 for a plurality of orientable arms 36, 37, 38 and 39 respectively sustaining a supporting device 40 for the thigh, a first fixing device 41 for the head of the femur, a second fixing
30 device 42 for the tibia and a supporting device 43 for the foot.

Orientable arms 36 - 39 comprise at both ends spherical joints that allow their angular adjustment as well as the angular adjustment of the devices that they

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are sustaining.

In particular, as shown in figure 6, fixing device 41 comprises a couple of hinges 45, 46 according to two axes orthogonal to each other and a couple of jaws 47 which have sharp edges 47a that can clamp for example the end portion of the femur diaphysis. Sharp edges 47a can slightly nick the bone and when tightened they block whichever further movement. This solution allows a not very much invasive fastening of the femur diaphysis.

In order to block the bone, dowels 48 are advantageously provided that engage with in screw threaded holes 49 provided on the walls of the jaws. Dowels 48, which have sharp end, for example conical end, penetrate slightly in the bone and keep it still co-operating with sharp edges 47a.

Second fixing device (fig. 5) for the tibia, instead, has a couple of clamps 42 which can be tightened by means of screws 42a and carry a couple of sticks not shown with screw threaded ends previously screwed into the exposed end of the bone.

Alternatively, also second fixing device 42 can be of the type with jaws and sharp edges as first fixing device 41.

Orientable arms 36, 37, 38, 39 can be easily secured in whichever angular position, using universal spanners, which tighten in a known way the relative spherical joints. The same can be done for the hinges and for the jaws of first fixing device 41. Orientable arms 36 - 39 are of known type available on the market, and then not described further.

The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying current knowledge, readily modify and/or adapt for various

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applications such specific embodiments without undue experimentation and without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended
5 within the meaning and range of equivalents of the disclosed embodiments. The means and materials for carrying out various disclosed functions may take a variety of alternative forms without departing from the invention. It is to be understood that the phraseology or
10 terminology employed herein is for the purpose of description and not of limitation.

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CLAIMS

1. Apparatus for guiding a tool, during bone cutting operations, for the execution of fixing and reference surfaces for a prosthesis, **characterised in that** it
5 comprises
- a robotised positioning unit having a plurality of degrees of freedom, suitable for being braked in a chosen position,
- a support head mounted to an end of said robotised
10 positioning unit,
- a mechanism carrying said tool and connected to said head, said mechanism being suitable for moving manually said tool according to predetermined degrees of freedom with respect to said head.
- 15 2. Apparatus according to claim 1, wherein said mechanism, with respect to said head, is capable of moving said tool in a plane, means being provided for translating said mechanism orthogonally to said plane.
3. Apparatus according to the previous claims, wherein
20 said mechanism comprises a first rod carrying said tool and a second rod, pivotally connected to said first rod.
4. Apparatus according to the previous claims, wherein said head comprises a fork support and said means for translating said mechanism orthogonally to said plane
25 comprise a micrometrical screw extending within said fork.
5. Apparatus according to claim 1, wherein said positioning unit comprises a basement suitable for being arranged under a surgical bed, means being provided for securing said basement to said surgical bed.
- 30 6. Apparatus according to claim 1, wherein an equipment for the support and the reference of limbs is provided, in particular for the support of the leg and for reference to the knee, comprising at least an orientable supporting arm mounted on a base, to the end of said arm opposite to said

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base at least a couple of jaws facing each other being connected in a way that can be oriented, said jaws being capable of adjustably clamping said limb and of supporting it firmly near the operation region.

5 7. Apparatus according to claim 5, wherein in said equipment at least a couple of jaws is provided at the end of said arm for fixing said limb, said jaws comprising sharp edges.

8. Equipment according to claims 6 o 7, wherein said jaws
10 have walls crossed by dowels for further clamping said limb.

9. Equipment according to claims from 6 to 8, wherein, an adjustable supporting arm for a support of the foot, an adjustable supporting arm for a support of the thigh and
15 an adjustable supporting arm for a support of the tibia are further comprised fixed to said base, said support for the foot comprising a pedal in a way that can be oriented connected to the relative arm, said support for the thigh comprising a saddle in a way that can be oriented
20 connected to the relative arm.

10. Equipment according to claim 9, wherein said support for the tibia comprises fixing means chosen among:

- sticks with screw threaded end and clamps for securing said sticks in a way that can be oriented connected to the
25 relative arm
- jaws having sharp edges facing each other suitable for adjustably clamping said limb and for supporting it firmly near the region of operation.

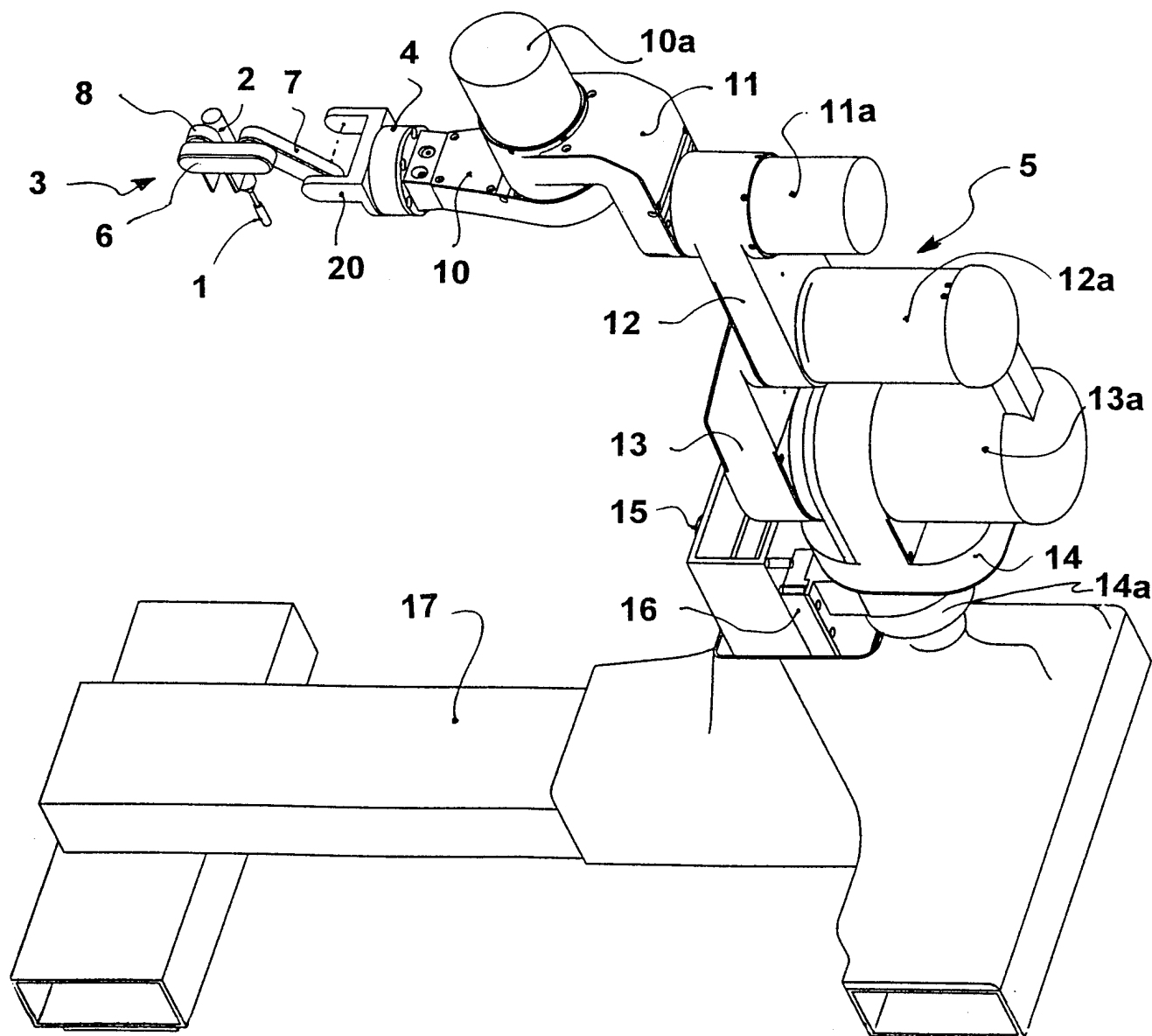
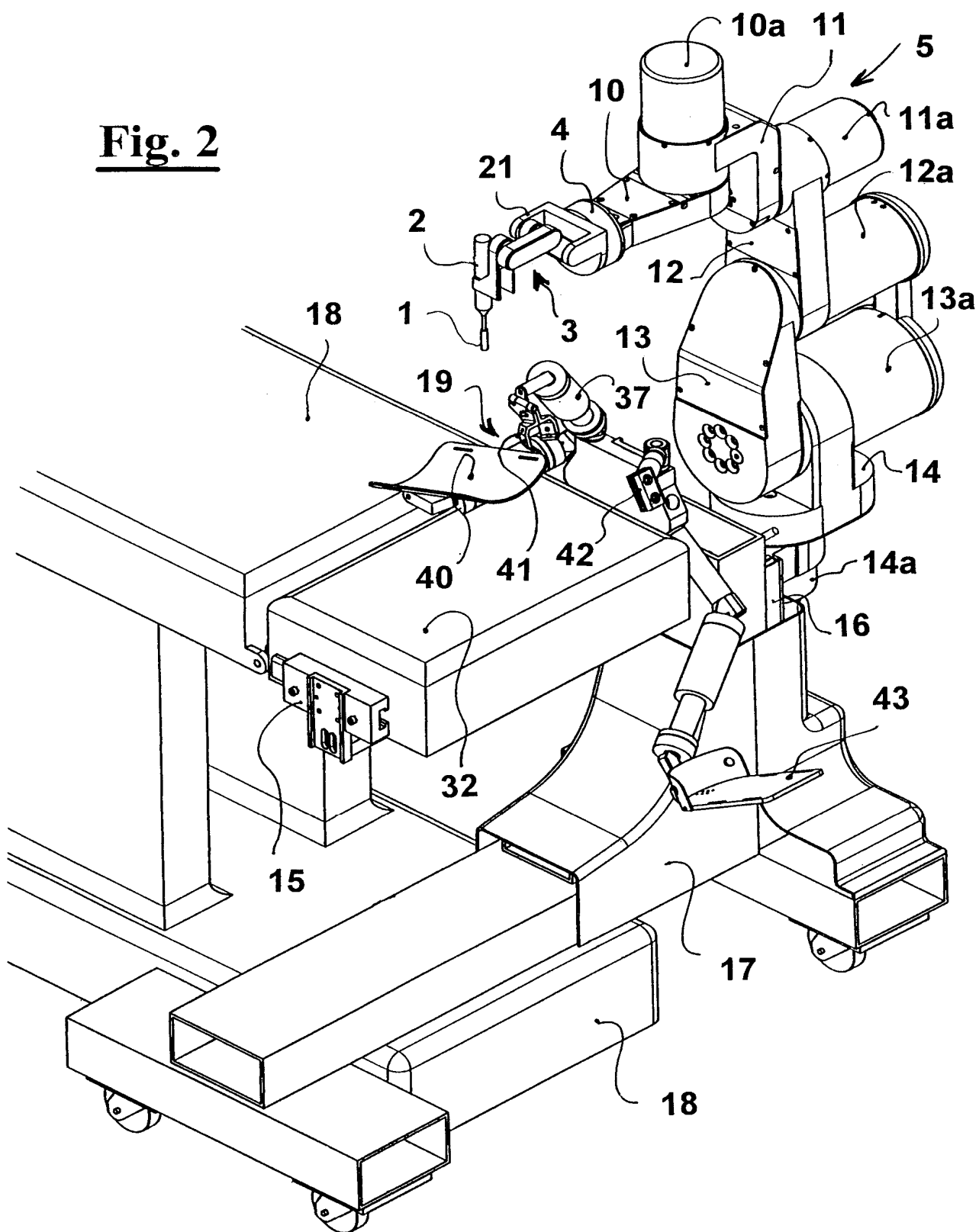
Fig. 1

Fig. 2

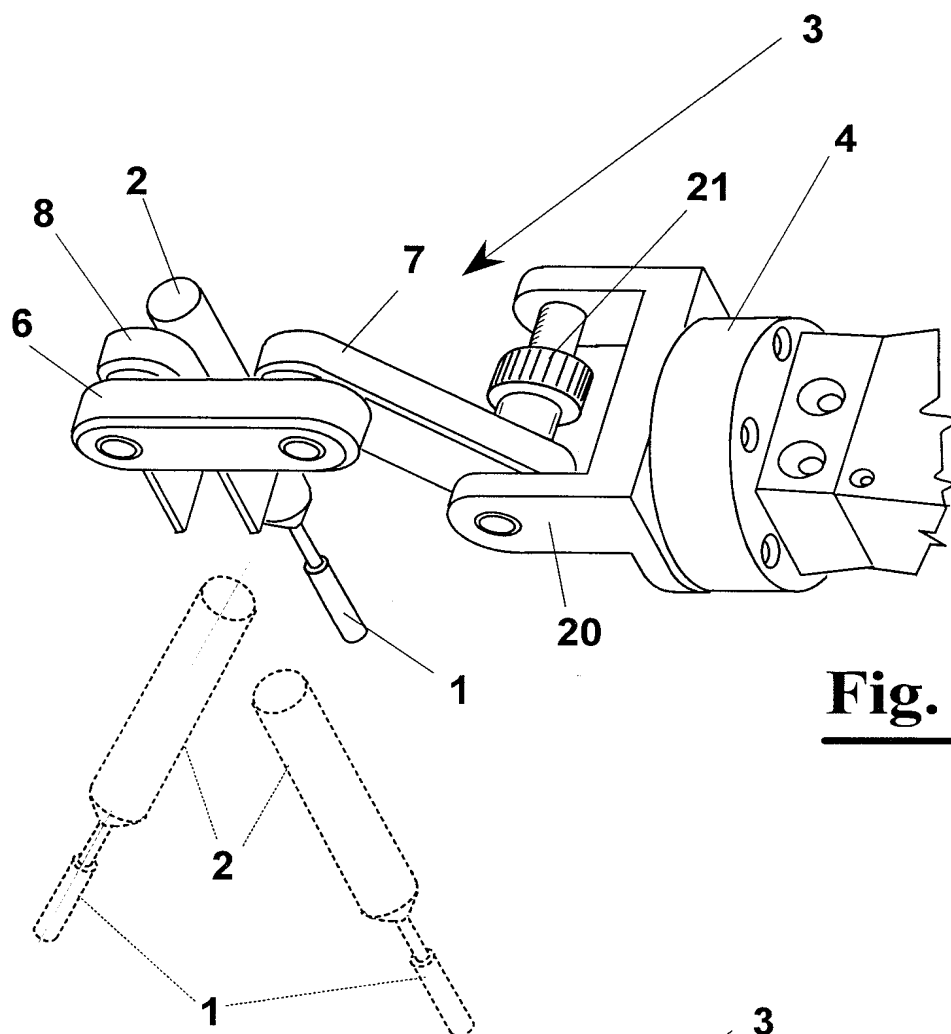


Fig. 3

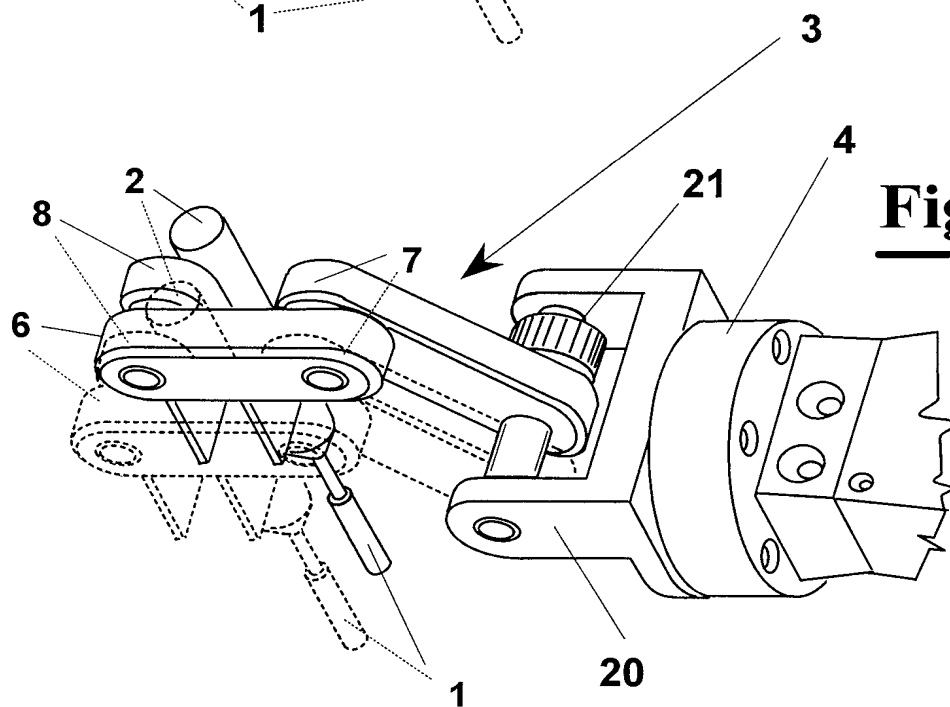


Fig. 4

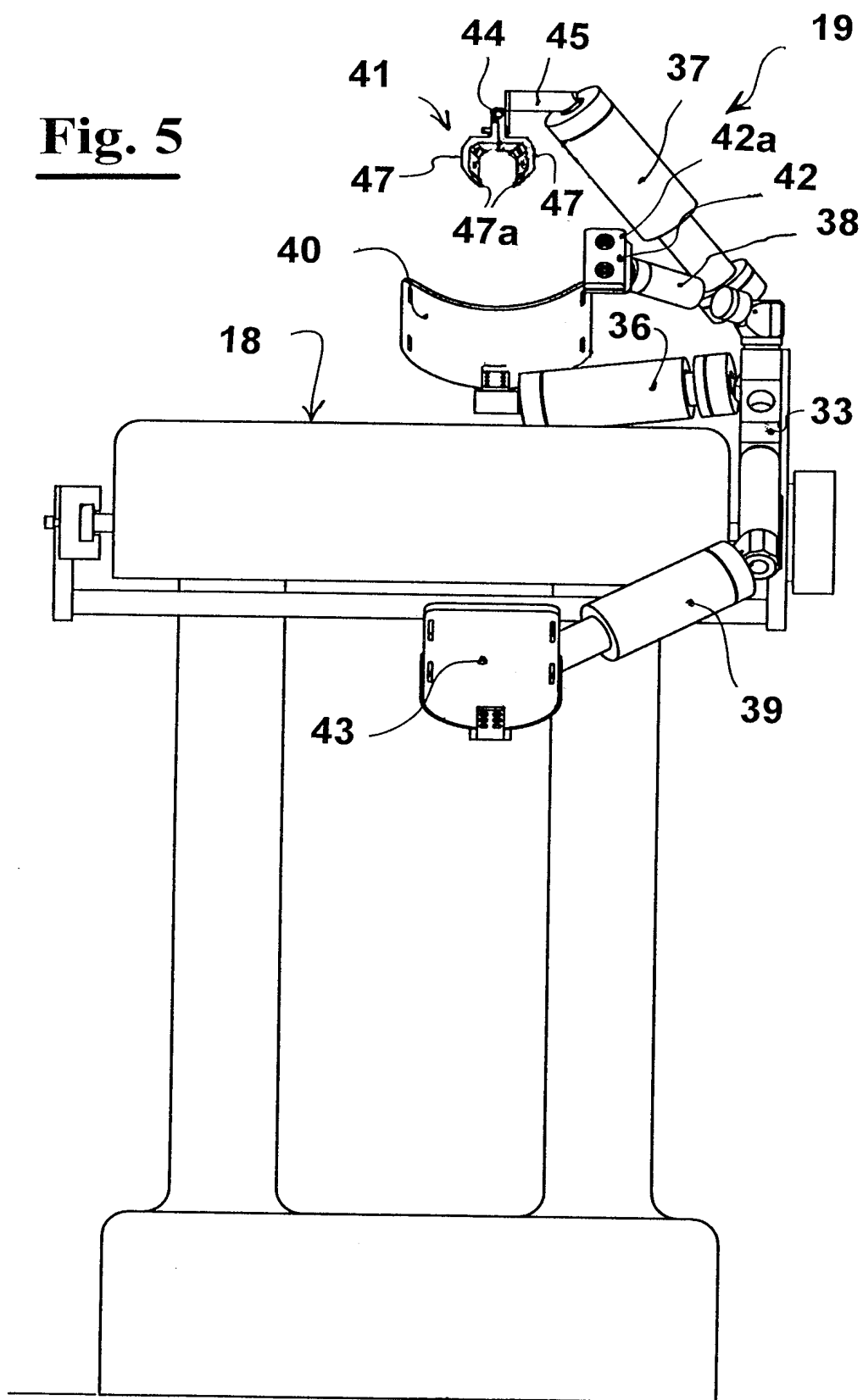
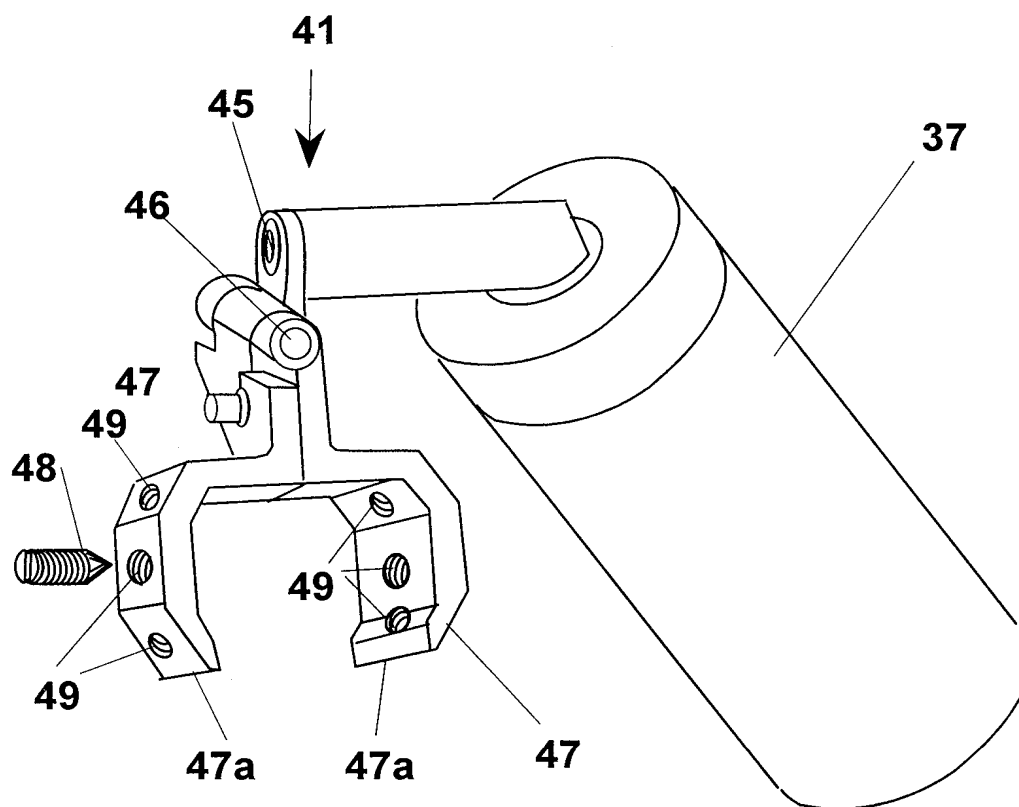
Fig. 5

Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 99/00446

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B17/15

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61G A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 979 949 A (BAUMGARTEN DONALD C ET AL) 25 December 1990 see column 9, line 41 - line 53 see column 14, line 32 - line 64 see column 15, line 42 - line 56; figures 3,4,7,15,19	1-6
A	WO 89 09570 A (ALBREKTSSON BJOERN ;WENNBERG STIG (SE)) 19 October 1989 see abstract; figure 6	1,6-10
A	US 5 010 900 A (AUCHINLECK GEOFFREY F ET AL) 30 April 1991 see column 5, line 46 - column 6, line 25; figure 1	1,9

☒ Further documents are listed in the continuation of box C.

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INTERNATIONAL SEARCH REPORT

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A	WO 95 16396 A (COMPUTER MOTION INC) 22 June 1995 see abstract; figures 1,2 ----	1-3,5
A	WO 95 00075 A (ANDRONIC DEVICES LTD) 5 January 1995 see abstract; figure 4 ----	1,6
A	EP 0 654 244 A (PALTIELI YOAV) 24 May 1995 see abstract; figure 2 ----	1-4
A	WO 97 34520 A (LEGRAND GEORGES) 25 September 1997 see abstract; figures 1-3 ----	1,6,9
A	US 4 428 571 A (SUGARMAN EDWARD D) 31 January 1984 see abstract; figure 1 -----	1,6,9

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No

PCT/EP 99/00446

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4979949 A	25-12-1990	US 5403319 A	04-04-1995
		US 5690635 A	25-11-1997
		US 5571110 A	05-11-1996
		US 5154717 A	13-10-1992
		US 5236432 A	17-08-1993
WO 8909570 A	19-10-1989	SE 468878 B	05-04-1993
		AT 96297 T	15-11-1993
		DE 68910305 D	02-12-1993
		EP 0393157 A	24-10-1990
		SE 8801310 A	12-10-1989
US 5010900 A	30-04-1991	NONE	
WO 9516396 A	22-06-1995	AU 7601094 A	03-07-1995
		US 5553198 A	03-09-1996
		US 5657429 A	12-08-1997
		US 5878193 A	02-03-1999
WO 9500075 A	05-01-1995	AU 680267 B	24-07-1997
		AU 7065894 A	17-01-1995
		CA 2165980 A	05-01-1995
		EP 0705074 A	10-04-1996
		JP 9500550 T	21-01-1997
		US 5611353 A	18-03-1997
EP 0654244 A	24-05-1995	US 5647373 A	15-07-1997
WO 9734520 A	25-09-1997	BE 1010080 A	02-12-1997
		AU 1918497 A	10-10-1997
		EP 0844862 A	03-06-1998
US 4428571 A	31-01-1984	CA 1174927 A	25-09-1984
		DE 3201066 A	02-12-1982
		FR 2505653 A	19-11-1982
		GB 2098484 A, B	24-11-1982
		JP 1707484 C	27-10-1992
		JP 3072305 B	18-11-1991
		JP 57190563 A	24-11-1982